UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EXELTIS USA DERMATOLOGY, INC., Plaintiff, v. ACELLA PHARMACEUTICALS, LLC, Defendant.	Civil Action No. 2:15-cv-07446-ES-MAH *(Document Filed Electronically)*

MEMORANDUM OF DEFENDANT ACELLA PHARMACEUTICALS, LLC IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, Defendant Acella Pharmaceuticals, LLC ("Acella") respectfully submits this Memorandum in Support of its Motion to Dismiss for Failure to State a Claim Upon Which Relief Can Be Granted.

BACKGROUND

Plaintiff alleges that it sells two prescription-only dermatological products under the brand names Hydro 35 and Salvax. Complaint, ¶ 16. Plaintiff also alleges that between September 2009 and April 2012, Acella and Plaintiff's predecessor, Quinnova Pharmaceuticals, Inc. ("Quinnova"), were parties to an Authorized Generic Promotion Agreement under which Quinnova allegedly provided Acella with the right to promote, distribute and sell a generic version of Salvax. Complaint, ¶¶ 20, 30. Plaintiff alleges that the agreement was amended during the term to "add Quinnova's Hydro 35 . . . to the list of products" in the agreement and to "add a second Salvax [product] to be rebranded and sold under the Acella name." Complaint, ¶ 22. It is difficult to discern from the Complaint if the agreement provided that Acella would be purchasing the Salvax product directly from Plaintiff, rebranding the product, and then reselling it under the Acella name.

The task of determining how the products were to be produced and how they were to be sold is made all the more difficult by the Plaintiff's failure to attach a

copy of the alleged written agreement to the Complaint. Acella assumes that a written agreement exists because Plaintiff refers to a "Confidentiality Clause" as "Section 6.1" in an apparent written agreement. Complaint, ¶ 23. As explained below, the only exhibits that were attached to the Complaint were package inserts showing publicly available information for Plaintiff's products and allegedly for Acella's competing products, such as the chemical components of the products, dosing information, and label warnings. Moreover, Plaintiff never alleges that the agreement itself is confidential, and even if it had so alleged, the agreement could have been filed with the Court under seal.

While it is impossible from the Complaint to determine the full relationship of the parties, or to determine each party's responsibilities to the other, the Complaint makes clear that, at least during the alleged term of the agreement, neither Plaintiff nor Acella was making Hydro 35. Instead, Plaintiff alleges that a third party by the name of Pharmasol Corporation manufactured the Hydro 35 product and then sold it to Acella, apparently for rebranding and then reselling. Complaint, ¶ 25. Plaintiff also asserts that it provided Pharmasol with "certain confidential and proprietary information concerning the Hydro 35® product that [Plaintiff] considered and continues to consider as its trade secrets, *i.e.*, the Proprietary Information." Complaint, ¶ 26. Nowhere does Plaintiff allege that it provided any confidential information to Acella.

Moreover, Plaintiff does not allege that Acella was contractually or otherwise legally prohibited from offering competing products to Salvax and Hydro 35, or that doing so violates any of Plaintiff's rights. Again, the failure to attach the purported agreement to the Complaint suggests that there was no covenant not to compete that would have prevented Acella from selling competing products after termination of the agreement. If there had been such a covenant, then it is expected that Plaintiff would have alleged a breach of that covenant. In fact, there is no allegation at all in the Complaint for breach of contract – the only allegations sound in tort (unfair competition, deceptive acts and practices, and trade secret misappropriation).

Plaintiff also never identifies or even suggests the subject matter of the alleged "trade secret" or "confidential information." Instead, Plaintiff only vaguely asserts allegations that Acella improperly accessed and used some unidentified confidential information of Quinnova to develop competing products. Complaint, ¶¶ 31-37. The Complaint completely avoids describing, specifically or broadly, the information that was supposedly confidential and that was allegedly misappropriated by Acella.

The sole identification of the alleged "Proprietary Information" is set forth in paragraph 1 as follows: "Exeltis's valuable proprietary information in connection with the formulation and manufacture of Exeltis's Hydro 35® and Salvax®

products (collectively, the 'Proprietary Information')." Complaint, ¶ 1. Plaintiff never says what information "in connection with the formulation and manufacture" of the products is confidential.

Later in the Complaint, Plaintiff refers to the information allegedly misappropriated by Acella, but still never identifies the information:

> 26. In order for Pharmasol to manufacture the Hydro 35® product, Quinnova disclosed to it *certain confidential and proprietary information concerning the Hydro 35®* product that Quinnova, and now Exeltis, considered and continues to consider as its trade secrets, *i.e.*, the Proprietary Information.
>
> 28. Upon information and belief, however, during those contacts with Pharmasol, Acella induced Pharmasol to disclose to it *certain Proprietary Information* concerning Hydro 35®, which Acella then used for an improper purpose.

Complaint, ¶¶ 26, 28.

Noticeably absent from any allegations in the Complaint, are any description of what type of information constitutes the so-called "Proprietary Information." There are no allegations that the proprietary information consists of processing and manufacturing steps or parameters, supplier information, component amounts, or other information that would typically be confidential and, in the absence of public disclosure, be protected as proprietary, trade secret information.

ARGUMENT

I. Legal Standard: A Claim Cannot Survive A Motion to Dismiss Unless It Is Plausible as Alleged

To survive a Rule 12(b)(6) motion to dismiss, an alleged claim must be plausible, and not just possible. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). This standard stems from Federal Rule of Civil Procedure 8(a)(2), which requires a plaintiff to plead "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Labels, conclusions, naked assertions, and recitations of the elements of a cause of action fail to meet this standard. *Id.* Furthermore, allegations that are merely consistent with a defendant's liability are insufficient because they fall "short of the line between possibility and plausibility of entitlement to relief." *Id.* (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007)) (quotation marks omitted). Thus, "[f]actual allegations must be enough to raise a right to relief above the speculative level," *Twombly*, 550 U.S. at 555 (2007), and the governing standard requires "more than a sheer possibility that a defendant has acted unlawfully, *Iqbal*, 556 U.S. at 678.

In considering a Rule 12(b)(6) motion, the Third Circuit employs a two-part analysis. First, the court must accept all of the complaint's well-pleaded facts as true while disregarding any legal conclusions. *See Fowler v.UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). Second, the court must determine whether the

facts, as alleged in the complaint, are sufficient to show that the plaintiff has a "plausible claim for relief." *Id.* Applying this standard as set forth below, it is clear that Plaintiff has failed to set forth a plausible claim, and that dismissal of the Complaint is warranted.

II. The Complaint Fails to Provide Any Plausible Factual Basis to Support the Claims

Each claim asserted by Plaintiff is premised upon the allegation that Acella improperly acquired and used something belonging to Plaintiff that was both confidential and proprietary. Plaintiff calls the information "Proprietary Information." Complaint, ¶¶ 42, 48, 53, 58, 66-67 (premising each asserted claim upon the alleged improper use of something defined as "Proprietary Information"). However, the Complaint never suggests or identifies even the general nature of such information and certainly never identifies the specific nature of such information. Such deficiencies fundamentally fail to give proper notice as required by the pleading standards.

In order for Acella to answer the Complaint, it must know what the information is that is allegedly confidential and proprietary and that it allegedly misappropriated. If not, then Acella cannot deny or admit that the information was confidential and proprietary and cannot deny or admit that it misappropriated the information.

Acella here is simply left scratching its head as to what it is being accused of doing beyond putting a competing product in the marketplace. Unless someone's trade secret, contract, or patent rights are violated, everyone has the right to market competing products. That is the basis of our free market system. *E.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 156 (1989) (explaining that the Supreme Court has "consistently reiterated the teaching . . . that ideas once placed before the public without the protection of a valid patent are subject to appropriation without significant restraint"). It sounds straightforward, but America was built on the ability of competitors to compete against each other in the absence of protectable rights. Without some sort of protection, competitors are free to copy each other's products. *See id.* Here, Plaintiff never identifies what it believes is protected and what Acella has allegedly misappropriated.

The only allegations in the Complaint that even provide a hint as to what Plaintiff believes may have been misappropriated are set forth in paragraphs 31, 32, 36, and 37:

> 31. Upon information and belief, Acella improperly used the Proprietary Information to allow it to manufacture, or have manufactured for it, and sell a flagrant and unauthorized copycat version of Hydro 35®. A copy of the package insert for Defendant's copycat product (the "Urea Product") is attached as **Exhibit A** hereto, and a copy of the package insert for Hydro 35® is attached as **Exhibit B** hereto.

> 32. A comparison of the package insert for Defendant's Urea Product (**Exhibit A**) and the package insert for Exeltis's Hydro 35® (**Exhibit B**) reveals that the two products contain the same active and inactive ingredient ingredients. Both Exeltis's Hydro 35® and Defendant's Urea Product contains urea in the identical amount (35%) and both contains the exact same inactive ingredients: dimethicone, ethylparaben, glycerin, lactic acid, methylparaben, phenoxyethanol, polysorbate 20, povidone, propylene glycol, propylparaben, purified water, stearic acid, trolamine, and propellants butane and propane.
>
> 36. Upon information and belief, Acella's possession and use of the Proprietary Information also allowed it to manufacture, or have manufactured for it, and offer for sale and sell a flagrant and unauthorized copycat version of Salvax®. A copy of the package insert for Defendant's copycat product (the "Salicylic Acid Product") is attached as **Exhibit C** hereto, and a copy of the package insert for Salvax® is attached as **Exhibit D** hereto.
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> 37. A comparison of the package insert for Defendant's Salicylic Acid Product (**Exhibit C**) and the package insert for Exeltis's Salvax® (**Exhibit D**) reveals that the two products contain the same active and inactive ingredients. Both Exeltis's Salvax® and Defendant's Salicylic Acid Product contains salicylic acid in the identical amount (6%) and both contains the exact same inactive ingredients: dimethicone, ethylparaben, glycerin, methylcellulose, methylparaben, phenoxyethanol, polyoxyl 40 stearate, polysorbate 20, polysorbate 80, povidone, propylene glycol, propylparaben, purified water, sodium citrate, sodium hydroxide, stearic acid, trolamine, and propellants butane and propane.

Complaint, ¶¶ 31, 32, 36, 37. In these paragraphs, Plaintiff suggests that Acella produced a competing product that has the same ingredients as Salvax and Hydro

35 and that the products contain "the same active" ingredients in the same amounts and "the exact same inactive ingredients." However, Plaintiff never alleges that the identification or amounts of the active ingredients or the identification of the inactive ingredients is confidential.

Of course, Plaintiff cannot make such an allegation because it is admitted in the Complaint that the ingredients and amount of active ingredients are shown on the Salvax and Hydro 35 packaging inserts. *See* Complaint, Ex. B (providing production information, including ingredients, for Plaintiff's Hydro 35 product) and Ex. D (providing production information, including ingredients, for Plaintiff's Salvax product); *see also See Southern Cross Overseas Agencies, Inc. v. Kwong Shipping Grp. Ltd.*, 181 F.3d 410, 426 (3d Cir. 1999) (providing that exhibits to complaints may be considered in deciding a motion to dismiss); *see also Goldenberg v. Indel, Inc.*, 741 F. Supp. 2d 618, 624 (D.N.J. 2010) (providing that, upon contradiction between allegations in the complaint and its attachments, the attachments control). Those inserts are obviously publicly available and the information on them, in the absence of patent protection, is available for all the world and any competitor to use in formulating products. That information, because it is publicly disclosed, cannot be protected by any trade secret or any claim of confidentiality. N.J.S.A. § 56:15-2 (providing that the New Jersey trade

secret statute only protects information as trade secret that "is not generally known to, and not being readily ascertainable by proper means, by other persons").

While the ingredient information could have been protected by a patent, assuming it met the standards of patentability, there is no allegation that Plaintiff owns such a patent or that there is any patent infringement. In addition, the information could have been protected vis-à-vis Acella if an enforceable non-compete agreement existed between Plaintiff and Acella. Again, there is no allegation that a non-compete has been violated and the failure to attach the alleged agreement to the Complaint suggests that there is no non-compete between the parties. Thus, there can be no dispute that Acella obtained or used any information regarding ingredients and active ingredient amounts that was confidential.

Beyond its allegation regarding the ingredient listings, Plaintiff never makes any allegation that even remotely suggests what other information, or even what type of information, it could contend is "proprietary" and that Acella allegedly and improperly obtained and used. With such product information being uncontrovertibly public, even having the same formulations as alleged by Plaintiff would not support Plaintiff's claims.[1] Absent any indication of any other type of

[1] Although the Court may not consider evidence outside of the pleadings in the context of this motion, Acella expressly reserves the right to establish that its products are distinct from Plaintiff's products. But, for purposes of this motion, dismissal is required even assuming Plaintiff's allegations of product sameness were considered as true.

"Proprietary Information" that may be at issue in this case, the Complaint is fundamentally insufficient. *See Educ. Impact, Inc. v. Danielson*, 2015 U.S. Dist. LEXIS 9467, at *16-17 (D.N.J. Jan. 28, 2015) (explaining that "a court need not credit either 'bald assertions' or 'legal conclusions' in a complaint when deciding a motion to dismiss").

Moreover, allegations that Acella "visited or contacted Pharmasol purportedly to obtain quality control information concerning manufacture of Hydro 35" still do not identify what "quality control information" was confidential. *See* Complaint, ¶ 27. Whether Pharmasol did or did not disclose such information to Acella is irrelevant if there is no allegation as to what the "quality control information was" and not allegation that the information was, in fact, confidential. Those are allegations that are never made in the Complaint. In addition, there are no similar allegations in the Complaint regarding unidentified "quality control information" with respect to Salvax. Therefore, no one knows what claims or facts Plaintiff may be asserting on that product at all. Simply put, Plaintiff has failed to provide sufficient notice for Acella to be able to defend itself. Accordingly, the Complaint should be dismissed.

This Court has dismissed cases in similar factual scenarios. For example, in *StrikeForce Techs., Inc. v. WhiteSky, Inc.*, 2013 U.S. Dist. LEXIS 96832, at *21-22 (D.N.J. July 11, 2013), similar allegations were found insufficient to sustain a

complaint. In that case, as with the current case, the parties had entered into a previous agreement under which StrikeForce, a software provider, licensed certain customized software versions to WhiteSky, an internet security company. *Id.* at *1. Subsequently, StrikeForce alleged that WhiteSky began using another company's software and, in doing so, WhiteSky improperly disclosed or used StrikeForce's confidentiality technology. As a result, StrikeForce asserted, *inter alia*, claims for breach of the confidentiality clause of the agreement and misappropriation of trade secrets.

The Court dismissed those claims for insufficient pleading. In so doing, the Court explained:

> Notably missing from the Complaint are non-conclusory factual allegations setting forth what actions WhiteSky allegedly took to violate these [agreement] provisions. At best, the Complaint parrots the language of the Agreement, asserting that in the course of replacing StrikeForce software with a competitor's anti-keylogging software, "WhiteSky is believed to have granted third parties access to StrikeForce's technology, to reuse, copy, replicate, and/or reverse-engineer StrikeForce's Customized Software." It also asserts that WhiteSky is developing software leveraging the StrikeForce technology and intellectual property. These amount to no more than the kind of "unadorned, the-defendant-unlawfully-harmed-me accusation[s]" that the Supreme Court held do not suffice to meet the pleading requirement of Rule 8(a) and withstand a motion to dismiss.

Id. (internal citations omitted). Plaintiff's conclusory allegations that Acella improperly used some of Plaintiff's unidentified information in some unidentified fashion to develop a competing product cannot is insufficient to plead a "plausible" claim.

This Court reached another similar result in *Diversified Indus., Inc. v. Vinyl Trends, Inc.*, 2014 U.S. Dist. LEXIS 61131, at *24-26 (D.N.J. May 1, 2014). In that case, a Vinyl Trends made and sold flooring products, including foam products for use as an underlayment for flooring. *Id.* at *2. Vinyl Trends' products included Eternity and Eternity SG Products. Similar to the present case, Vinyl Trends alleged that its competitor, Diversified Industries, had misappropriated its trade secrets. In particular, Vinyl Trends merely alleged that both companies used the same foam supplier, which Vinyl Trends asserted allowed Diversified Industries to obtain confidential information about Vinyl Trends' products. In advancing these theories, Vinyl Trends pled, upon information and belief, that its competitor had "obtained information concerning the sound rating and VOC content of the Eternity and Eternity SG products, and also obtained information concerning other product specifications as well as the development, marketing and sale of the Eternity and Eternity SG products." *Id.* at *24-25.

In dismissing the case, the Court noted numerous deficiencies with the complaint. Those deficiencies, as in this case, included that the allegations failed

"to identify with any specificity the allegedly misappropriated information." *Id.* In this case, Plaintiff has provided even less information than in *Diversified* by failing to identify any information (or even any type of information) regarded as a confidential or a trade secret rising to the level of the information found insufficient in the *Vinyl Trends* case. *See Iqbal*, 556 U.S. at 681 (explaining that "[i]t is the conclusory nature of [Plaintiff's] allegations, rather than their extravagantly fanciful nature, that disentitles them to the presumption of truth")

In sum, such inadequate allegations fail to give Acella "fair notice" as required by the Federal Rules. *See Twombly*, 550 U.S. at 555 (observing that Rule 8(a)(2) requires a pleading sufficient to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests" (quoting *Conley v. Gibson*, 355 U.S. 41, 41 (1957))). Furthermore, such allegations "are 'merely consistent with' [Acella's alleged] liability, [but] [they] 'stop[] short of the line between possibility and plausibility of 'entitlement to relief.'" *See Iqbal*, 556 U.S. at 648 (quoting Twombly, 550 U.S. at 557). As such, the claims must be dismissed.

III. Plaintiff's Claims Are Further Evidenced as Implausible In View of Other Public Disclosures

As noted above, each of Plaintiff's claims necessarily hinges upon the generic allegation that Acella improperly obtained and used some of Plaintiff's undefined "Proprietary Information." However, Acella has learned that, despite not alleging patent infringement here, Plaintiff has patents and/or published patent

applications relating to a urea product (such as its Hydro 35) and a salicylic acid product (such as its Salvax), and the Court may consider the public disclosures in those documents in resolving this motion. *See Clements v. Sanofi-Aventis, U.S., Inc.*, 2015 U.S. Dist. Lexis 75918, at * 15 (D.N.J. June 11, 2015); *see also Hoganas A.B. v. Dresser Indus.*, 9 F.3d 948, 954 n.27 (Fed. Cir. 1993) (taking judicial notice of a patent). Given those previous publications by Plaintiff's predecessor concerning the types of products at issue in this case, the legally unsupportable nature of those vague and generic allegations are even more apparent and implausible.

In particular, Plaintiff is listed as the owner of a U.S. Patent No. 8,470,887 (Ex. 1 attached hereto) and U.S. Published Patent Application No. 2010/0092400 (Ex. 2 attached hereto). Those published documents respectively disclose a urea product and a salicylic acid product having the nearly identical components disclosed in Hydro 35 and Salvax. Therefore, nothing in the ingredient listing is confidential.

But, in addition to the ingredient listings, patents are required to disclose how to make and use the product. *See* 35 U.S.C. § 112 (requiring a patent to include a "written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

person skilled in the art to which it pertains . . . to make and use the same").[2] It is beyond dispute that such patents and published patent application places information in the public domain and destroys any trade secret protection for information disclosed in or readily ascertained from its disclosure. *E.g.*, *On-Line Techs., Inc. v. Bodenseewerk Perkin-Elmer GmbH*, 386 F.3d 1133, 1141 (Fed. Cir. 2004) (providing that information contained in published patent disclosures "is ordinarily regarded as public and not subject to protection as a trade secret"); *see also Tank Tech, Inc. v. Neal*, 2007 U.S. Dist. LEXIS 53066 (E.D. Mo. July 23, 2007) (observing that filing a patent application for a system destroys trade secret protection for that system); *accord Restatement of Unfair Competition*§ 39 cmt. f (1995) (explaining that "information that is disclosed in a patent or contained in published materials reasonably accessible to competitors does not qualify for [trade secret] protection"). Accordingly, unless there is a claim for patent infringement (and there is none here), the disclosures in the Plaintiff's patents may be utilized by competitors to make competing products.

Furthermore, in the same manner, the New Jersey Trade Secret Act only protects information as trade secret that "is not generally known to, and not being readily ascertainable by proper means, by other persons." N.J.S.A. § 56:15-2.

[2] This excerpt is from the applicable law at the time that the relevant patent applications were filed, which was prior to the more recent America Invents Act that modified certain provisions in ways irrelevant to this issue.

Here, absent any detailed pleading from Plaintiff, such publications legally destroy any credible argument by Exeltis that trade secrets exist in its products and, at the very minimum, it certainly has not pled otherwise. *See Bonito Boats*, 489 U.S. at 156 (observing that "we have consistently reiterated the teaching of Sears and Compco that ideas once placed before the public without the protection of a valid patent are subject to appropriation without significant restraint.").[3]

IV. Even if Plaintiff's Allegations Are Accepted As True, Plaintiff's Unfair Competition-Type Claims (Counts 1 – 3) Are Factually and Legally Unsupported by the Complaint

Plaintiff's unfair competition claims also require dismissal on the entirely independent basis that no facts alleged in the Complaint, even if considered sufficiently pled and assumed true, can support the legal elements required for an unfair competition claim. In particular, Plaintiff has asserted a Lanham Act claim for unfair competition in violation of 15 U.S.C. § 1125(a) (First Claim for Relief) and a claim for common law unfair competition (Third Claim for Relief), which are coextensive and considered herein together. *See Spark Innovators Corp. v. Tele Marketers, Inc.*, 2014 U.S. Dist. LEXIS 83438, at *7 (D.N.J. June 19, 2014) (explaining that "[t]he test for unfair competition under New Jersey common law

[3] While Plaintiff may attempt to argue that trade secrets may exist for a product simultaneously with patent applications, this underscores the principal basis of this motion that Plaintiff has not even generically identified any information or category of information that may be even remotely subject to trade secret protection. On that basis alone, dismissal is mandated despite any such argument from Plaintiff.

'is identical to the test for federal unfair competition and infringement; whether a likelihood of confusion exists.'" (quoting *Apollo Distributing Co. v. Jerry Kurtz Carpet Co.*, 696 F. Supp. 140, 143 (D.N.J. 1988))). These claims find no support in law based upon the allegations pled in the Complaint.

In particular, these claims are premised upon a party providing a product in a manner that confuses customers as to the source of the product or as to affiliation amongst sources. Specifically, the statute provides in relevant part:

> (1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—
>
> > **(**A) is ***likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person***, or
> >
> > (B) in commercial advertising or promotion, ***misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities***, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a). In short, this statute protects against one company confusing consumers or misrepresenting the source of products and is entirely inapplicable to this case based upon Plaintiff's allegations in the Complaint.

Specifically, Plaintiff has made no allegation that Acella acted in a manner to confuse consumers or made false statements about its own goods or any person's goods. There is no allegation that Acella used Plaintiff's trademarks, attempted to lead consumers to believe that Acella's products were affiliated with Plaintiff, or took any other action to create any such confusion amongst consumers. The mere existence of competing products does not in any way suggest a violation of the Lanham Act. Similarly, based on the allegations, even if accepted, there is no basis to even remotely conclude that Plaintiff's goodwill or reputation has in any manner been impermissibly harmed by the mere existence of a competing product on the market. *See* Complaint at ¶ 44 (identifying the loss of goodwill and reputation as the alleged injury suffered).

No fact has been alleged to support these claims, and the claims are not plausible. Merely referencing Acella's product as a "copycat" does not in any way suggest that consumers would not appreciate that each company's products (having their own brand names and properly identified with the correct source) are being provided from different sources. *See Educ. Impact, Inc.*, 2015 U.S. Dist. LEXIS 9467, at *16-17 (D.N.J. Jan. 28, 2015) (explaining that "a court need not credit either 'bald assertions' or 'legal conclusions' in a complaint when deciding a motion to dismiss"). These claims are simply legally deficient based upon the total

lack of any supporting facts alleged in the Complaint, and dismissal is both appropriate and necessary.

For the same reason, Plaintiff's unfair competition claim under N.J.S.A. § 56:4-1 *et seq*. (Second Claim for Relief) cannot be maintained. The sole conclusory allegation pled in the Complaint concerning this claim is that Acella's alleged conduct appropriated the "name, reputation, and goodwill" of Exeltis. Complaint, ¶ 48. However, no allegation was made (or could be made) that Acella in any way used any name or trademark of Exeltis or in any other way improperly impinged upon its goodwill. There is no allegation that Acella's product relied upon the reputation or goodwill of Exeltis and, in fact, the exhibits to the Complaint indicate otherwise when Plaintiff admits that Acella used its own branding for all products.

Legitimate competition with a competing product is not unlawful, and permitting such unsupported theories by Exeltis would suggest that no company could have competing products without violating this statute. Thus, Plaintiff's unfair competition claims lack any factual basis in the Complaint and must be dismissed.

V. Plaintiff's Vague and Ambiguous Fourth Claim for Relief (Common Law Deceptive Acts and Practices) Is Inadequately Pled and Fails to Provide Any Reasonable Notice to Acella of the Claim

Plaintiff's "Fourth Claim for Relief" is indecipherable. With only scant and conclusory allegations, this claim purports to allege "deceptive acts and practices" in violation of the common law of the State of New Jersey. The legal nature of this claim is neither identified nor apparent from the Complaint. To the extent that this claim is redundant with the previously-discussed claims, it must fail for the same reasons discussed above. To the extent that this claim is different, it is entirely unclear what legal theory is asserted by this vague and ambiguous claim. Such generalized allegations and uncertain legal foundations fail to provide any notice to Acella and cannot be countenanced. *See Twombly*, 550 U.S. at 555 (observing that Rule 8(a)(2) requires a pleading sufficient to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests" (quoting *Conley*, 355 U.S. at 41)).

CONCLUSION

For at least the foregoing reasons, Plaintiff's Complaint fails to raise a plausible claim for relief and to provide adequate notice to Acella of the claims. As such, dismissal of the Complaint pursuant to Rule 12(b)(6) is warranted and respectfully requested.

Respectfully submitted,

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for Defendant Acella Pharmaceuticals, LLC certifies that, to the best of his knowledge, the matter in controversy is not subject of another action pending in any court or of any pending arbitration or administrative proceeding.

/s/ Christopher R. Kinkade
Christopher R. Kinkade

Dated: December 7, 2015

EXHIBIT 1

US008470887B2

(12) **United States Patent**
Silvander

(10) **Patent No.: US 8,470,887 B2**
(45) **Date of Patent: *Jun. 25, 2013**

(54) **UREA FOAM**

(75) Inventor: **Mats Silvander**, Uppsala (SE)

(73) Assignee: **Quinnova Pharamaceuticals, Inc.**, Jamison, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/326,761**

(22) Filed: **Dec. 15, 2011**

(65) **Prior Publication Data**

US 2012/0087873 A1 Apr. 12, 2012

Related U.S. Application Data

(63) Continuation of application No. 12/016,371, filed on Jan. 18, 2008, now Pat. No. 8,101,664.

(60) Provisional application No. 60/885,677, filed on Jan. 19, 2007.

(51) **Int. Cl.**

A61K 9/12	(2006.01)
A61K 31/16	(2006.01)
A61K 31/17	(2006.01)

(52) **U.S. Cl.**

USPC **514/588**; 514/579; 514/861; 514/863; 514/945; 424/45

(58) **Field of Classification Search**

USPC 514/579, 588, 861, 863, 945; 424/45

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,666,863	A	5/1972	Swanbeck
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(57) **ABSTRACT**

Provided, among other things, is a delivery module for a non-greasy, water-based urea composition comprising: an aerosol delivery device; within the aerosol delivery device, the urea composition comprising 20% or more urea by weight, non-greasy lipophilic component(s), and a frothing agent, the urea composition having a viscosity low enough to support aerosol delivery, and the urea composition effective to form a foam upon propellant-driven aerosol delivery; and within the aerosol delivery device, a propellant.

24 Claims, No Drawings

UREA FOAM

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a Continuation of and claims the benefit of priority of pending U.S. patent application Ser. No. 12/016,371, filed on Jan. 18, 2008, which claims priority to Provisional application Ser. No. 60/885,677, filed Jan. 19, 2007, both of which are incorporated herein by reference in their entirety.

TECHNICAL FIELD

The present invention relates to foam-forming composition of urea, which can be used to treat psoriasis, and thickened areas of the soles, elbows, knees and the like.

BACKGROUND

Urea, especially in high concentrations, can be used to treat dry scaly skin, or skin that has thickened to a non-cosmetic or uncomfortable degree. This activity has been attributed to the ability of urea to solubilize and denture protein. Urea can be used to treat xerosis, ichthyosis (e.g., ichthyosis vulgaris), psoriasis, atopic dermatitis, and the like. Such treatment can include itch relief, at least temporary itch relief.

Dermatological compositions of concentrated urea have been formulated in oily bases. Such a oil-based formulations provide a protective layer and localize the urea on the skin. Despite the bias in the industry to formulate in oil-based ointments, Applicant sought to make a water-based, foam-forming composition.

In seeking to formulate a water-based, foam-forming composition, it was discovered that high urea concentrations destabilize formulations that are otherwise stable, water-based dermatological formulations, yielding compositions that form sediments to a degree that makes proper dispensing difficult. Described herein are parameters within which one can formulate stable, water-based compositions of urea at high concentration.

SUMMARY

Provided, among other things, is a delivery module for a non-greasy, water-based urea composition comprising: an aerosol delivery device; within the aerosol delivery device, the urea composition comprising 20% or more urea by weight, non-greasy lipophilic component(s), and a frothing agent, the urea composition having a viscosity low enough to support aerosol delivery, and the urea composition effective to form a foam upon propellant-driven aerosol delivery; and within the aerosol delivery device, a propellant.

Further provided, among other things, is a urea composition comprising: urea 20-50%; fatty acid(s) and/or analogous alkyl amine(s) 1-5%; hydrophilic polymer(s) 0.5-1.5%; titrant, as needed in amount effective to substantially neutralize the fatty acid(s) or alkyl amine(s); frothing agent 0.3-4%; and humectant 0.5-7%.

Also provided, among other things, is a method of treating dermatitis, psoriasis, xerosis, ichthyosis, eczema, keratosis, keratoderma, dry and rough skin, corns, calluses, damaged, or ingrown and devitalized nails comprising applying to affected skin a foamed, non-greasy, water-based urea composition comprising: 20% or more urea by weight, non-greasy lipophilic component(s), and a frothing agent, the urea composition having a viscosity low enough to support aerosol delivery, and the urea composition effective to form a foam upon propellant-driven aerosol delivery.

DETAILED DESCRIPTION

Urea can be present, for example, in amounts from about 20% by weight to to about 50% by weight, or to about saturation (in the composition). Unless otherwise detailed, all amount percentages presented in this specification are weight percentages. In certain embodiments, urea is 20% or more, 25% or more, 30% or more, 31% or more, or 32% or more, or 33% or more, or 34% or more, or 35% or more, or 36% or more, or 37% or more, or 38% or more, or 39% or more of the urea composition. In certain embodiments, urea is 49% or less, or 48% or less, or 47% or less, or 46% or less, or 45% or less, or 44% or less, or 43% or less, or 42% or less, or 41% or less of the urea composition.

It is believed that urea formulated in an aqueous solution can facilitate urea absorption on skin. A non-greasy skin-feel, which can be achieved with the present formulation, allows for more frequent applications than would be cosmetically acceptable with oil based formulations.

The composition can contain lipophilic components that are believed to help distribute urea on and into the skin. A major portion of such lipophilic components can be amphiphates in amounts effective to stabilize the lipophilic components in solution and/or emulsified. Example amphiphates are fatty acids, which can be substantially or essentially ionized, wherein the salt is soluble in the aqueous solution of the urea composition. Further examples are alkyl amines with one alkyl per amine having a size distribution analogous to that of an appropriate fatty acid composition. Further examples are nonionic detergents.

The fatty acid can, for example, be of any composition found in a natural source, including hydrolysis of esterified fatty acids. Or, the fatty acid component can be hydrogenated to remove substantially all or a portion of any unsaturation. In certain embodiments, the fatty acid component or the alkyl moiety of the alkyl amine component is selected such that 50 mole % or more is C12 or higher, or C14, or C16 or higher. In certain embodiments, the fatty acid component or the alkyl moiety of the alkyl amine component is selected such that 50 mole % or more is C22 or lower, or C20 or lower, or C18 or lower. In certain embodiments, 75 mole % or more of the fatty acid component is from C12 or C14 or C16 to C22 or C20 or C18. In certain embodiments, 80 mole % or more, 85 mole % or more, 90 mole % or more, 95 mole % or more, 97 mole % or more, 98 mole % or more, or 99 mole % or more, meets one of the size parameters of this paragraph.

For carboxylic acid containing lipophilic components, useful salts include the alkali metal salts such as sodium or potassium salts; ammonium salts; salts formed with suitable organic bases, such as amine salts (such as triethyl amine, triethanol amine, or the like) and quaternary ammonium salts; or the like. Bivalent or trivalent salts can be used where they do not adversely affect solubility. For amine-containing lipophilic components, useful salts include maleates, fumarates, lactates, oxalates, methanesulfonates, ethanesulfonates, benzenesulfonates, tartrates, citrates, halides (e.g., hydrochlorides, hydrobromides), sulfates, phosphates, nitrates, and the like. As needed, the lipophilic components are provided such that a sufficient amount of constituent ionizable molecules are in ionized (salt) form to provide solubility. Such ionized forms can be prepared by adding a titrant, though recitations of compositions described by such titration include the equivalent compositions formed by pre-formed salts or otherwise.

The lipophilic component may include 50% or less of a more hydrophobic component, such as one that can be termed an emollient. This more hydrophobic component can be, for example, 45% or less, or 40% or less, or 35% or less, or 30% or less, or 25% or less, or 20% or less, of the lipophilic component.

In certain embodiments, the lipophilic component is 1% or more, or 1.5% or more, or 2% or more, or 2.5% or more, or 3% or more of the urea composition. In certain embodiments, the lipophilic component is 8% or less, 7.5% or less, 7% or less, 7.5% or less, 6% or less, 5.5% or less, 5% or less, or 4.5% or less, or 4% or less, or 3.5% or less of the urea composition. Where the lipophilic component comprises, as predominant component(s), fatty acids or analogous alkyl amines, these predominate components can be 1% or more, or 1.5% or more, or 2% or more, or 2.5% or more, or 3% or more of the urea composition; and 5% or less, or 4.5% or less, or 4% or less, or 3.5% or less of the urea composition.

An emollient, if present, can be a silicone oil such as polydimethylsiloxane (i.e., dimethicone), petrolatum, or the like. In certain embodiments, the emollient(s) are 0.5% or more, or 0.6% or more, or 0.7% or more, or 0.8% or more, or 0.9% or more, or 1% or more of the urea composition. In certain embodiments, the emollient(s) are 2% or less, or 1.9% or less, or 1.8% or less, or 1.7% or less, or 1.6% or less, or 1.5% or less, or 1.4% or less, or 1.3% or less, or 1.2% or less, or 1.1% or less, or 1% or less of the urea composition.

A non-greasy feel is measured in reference to oil-based ointments and by comparison of the feel of the Example composition (described in the Example below), applied to skin at 1 mg/cm^2, compared to the oil-based product described in the Table at Column 3 of U.S. Pat. No. 5,919,470 (Bradley Pharmaceuticals, Inc.), applied in the same amount. While the feel of compositions of the invention may vary, in making the comparison between the non-greasy standard, the greasy standard, and the prospective non-greasy composition, it will be apparent which category the prospective composition falls within. The non-greasy skin feel may be moist and smooth feeling, but the difference in greasy feel relative to the greasy comparative shall be clear.

The hydrophilic polymer(s) can be any non-toxic water soluble polymer(s) that (in the aggregate) stabilize foam and contribute to film formation on the skin. Examples include polyvinyl pyrrolidone, polyethylene glycol, starch, water-soluble derivatives of starch, cellulose, methyl cellulose, hydroxymethylcellulose, other water-soluble derivatives of cellulose, carbomers, or the like. For polyvinyl pyrrolidone, for example, useful average molecular weights include from 8,000 to 63,000, such as about 38,000. For all polymers used in the composition, the size should be sufficient to limit penetration of the horny layer of the skin, if skin penetration is an issue for the given polymer.

In certain embodiments, hydrophilic polymer(s) are 0.2% or more, 0.3% or more, 0.4% or more, 0.5% or more, or 0.6% or more, or 0.7% or more, or 0.8% or more, or 0.9% or more, or 1% or more, or 1.5% or more of the urea composition. In certain embodiments, the hydrophilic polymer(s) are 3% or less, 2.5% or less, 2% or less, 1.5% or less, or 1.4% or less, or 1.3% or less, or 1.2% or less, or 1.1% or less, or 1% or less of the urea composition.

The composition can also contain a humectant, such as glycerol, propylene glycol, other polyols, polydextrose, lactic acid, or the like. In certain embodiments, humectant(s) are 0.5% or more, or 0.6% or more, or 0.7% or more, or 0.8% or more, or 0.9% or more, or 1% or more, or 1.2% or more, or 1.4% or more, or 1.6% or more, or 1.8% or more, or 2% or more, or 2.5% or more, or 3% or more, or 3.5% or more, or 4% or more of the urea composition. In certain embodiments, the humectant(s) are 7% or less, or 6.5% or less, or 6.0% or less, or 5.8% or less, or 5.6% or less, or 5.4% or less, or 5.2% or less, or 5% or less of the urea composition.

The frothing agent can be, for example, a non-ionic detergent such as Polysorbate 20, polyoxyethylene sorbitan fatty acid esters, sorbitol fatty acid esters, or the like. In certain embodiments, the frothing agent(s) are 0.3% or more, or 0.4% or more, or 0.5% or more, or 0.6% or more, or 0.7% or more, or 0.8% or more, or 0.9% or more, or 1% or more, or 1.1% or more, or 1.2% or more, or 1.3% or more, or 1.4% or more, or 1.5% or more, or 1.6% or more, or 1.7% or more, or 1.8% or more, or 1.9% or more, or 2.0% or more, or 2.1% or more, or 2.2% or more, or 2.3% or more of the urea composition. In certain embodiments, the frothing agent(s) are 4% or less, 3.5% or less, 3% or less, 2.9% or less, 2.8% or less, 2.7% or less, 2.6% or less, 2.5% or less, 2.4% or less, 2.3% or less, 2.2% or less, 2.1% or less, 2% or less, 1.9% or less, 1.8% or less, 1.7% or less, 1.6% or less, 1.5% or less, or 1.4% or less, or 1.3% or less, or 1.2% or less, or 1.1% or less, or 1% or less, or 0.9% or less, or 1.8% or less of the urea composition.

In certain embodiments, the urea composition can contain soothing agent(s) such as homogenized oatmeal. In certain embodiments, the soothing agent(s) are 0.02% or more, 0.03% or more, 0.04% or more, 0.05% or more, or 0.06% or more, or 0.07% or more, or 0.08% or more, or 0.09% or more, or 0.01% or more of the urea composition. In certain embodiments, the soothing agent(s) are 0.2% or less, or 0.15% or less, or 0.14% or less, or 0.13% or less, or 0.12% or less, or 0.11% or less, or 1% or less of the urea composition.

Additional optional ingredients include sunscreens, antimicrobial agents or preservatives, fragrances, and the like.

Suitable propellants include, for example, propane, butane, isobutene, other hydrocarbons, hydrofluorocarbons, chlorofluorocarbons (Cl/F/(H)/C), and the like.

The amount of urea composition applied to an affected area of skin can vary with a number of variables including the condition of the skin, the sensitivity of the patient or the area of skin, and the like. In any single administration, the delivery device can deliver to the affected area an appropriate layer of foam that provides an appropriate amount of urea composition. The aerosol-driven foam can be applied to the affected area and rubbed into the skin until absorbed. Typically, the composition is applied twice a day.

Topically applied urea is believed to dissolve the intercellular matrix of the skin which results in enhanced shedding of scaly, dry skin and thus a softening of the hyperkeratotic areas of the skin. Urea topically applied to the nail plate has a similar effect on the intercellular matrix of the nail plate. Topically applied urea can be used for enzymatic debridement and promotion of normal healing of surface lesions, particularly where healing is retarded by local infection, necrotic tissue, fibrinous or purulent debris, or eschar. Topically applied urea is useful for the treatment of hyperkeratotic conditions such as dermatitis (e.g., atopic dermatitis), psoriasis, xerosis, ichthyosis, eczema, keratosis, keratoderma, dry, rough skin, corns and calluses, damaged, ingrown and devitalized nails, and the like.

EXAMPLES

Example 1

The following composition is formulated:

Component	Wt. %
Water	46.47
PVP	0.95
Oatmeal	0.1
Stearic acid	3.13
Propylene Glycol	2.9
Glycerin	2.0
Dimethicone	1.0
Phenonipe ™ (a mixture of preservatives from _)	0.5
Triethanol amine	0.65
Polysorbate 20	2.30
Urea	40.0
Total	100.00

The oatmeal is homogenized in a portion of the water. The remaining water is heated to 70° C. With stirring, the following were added in order: PVP, oatmeal slurry, and stearic acid. Then, the remainder is added less the urea. The temperature controller is set to 60° C., allowing the temperature to decline. When the temperature is down to 60° C., the urea is added in portions as follows: 8 parts of 100, 8 parts, 8 parts, 16 parts, 16 parts, 16 parts, remainder. Care is taken that the temperature is 60° C. or higher on each addition. The regulator is then set to 25° C., and the composition is agitated for 30 minutes. Aerosol dispensers can be filled with the composition at 25° C.

Or, The water is heated to 70° C. With stiffing, the following were added in order: oatmeal, PVP, and stearic acid. Then, the remainder is added less the urea. The temperature controller is set to 60° C., allowing the temperature to decline. When the temperature is down to 60° C., the urea is added in portions as follows: 8 parts of 100, 8 parts, 8 parts, 16 parts, 16 parts, 16 parts, remainder. Care is taken that the temperature is 60° C. or higher on each addition. After the last urea addition, and after the temperature has again reached 60° C., the regulator is then set to 25° C., and the composition is agitated for 30 minutes. Aerosol dispensers can be filled with the composition at 25° C., and with stiffing during filling.

Example 2

The following composition is formulated:

Component	Wt. %
Water	48.07
PVP	0.95
Oatmeal	0.1
Stearic acid	3.13
Propylene Glycol	2.9
Glycerin	2.0
Dimethicone	1.0
Phenonipe ™ (a mixture of preservatives from _)	0.5

-continued

Component	Wt. %
Triethanol amine	0.65
Polysorbate 20	0.70
Urea	40.0
Total	100.00

The oatmeal is homogenized in a portion of the water. The remaining water is heated to 70° C. With stirring, the following were added in order: PVP, oatmeal slurry, and stearic acid. Then, the remainder is added less the urea. The temperature controller is set to 40° C., allowing the temperature to decline. When the temperature is down to 50° C., the urea is added in portions as follows: 8 parts of 100, 8 parts, 8 parts, 16 parts, 16 parts, 16 parts, remainder. Care is taken that the temperature is 40° C. or higher on each addition. The regulator is then set to 25° C., and the composition is agitated for 30 minutes. Aerosol dispensers can be filled with the composition at 25° C.

Or, The water is heated to 70° C. With stiffing, the following were added in order: oatmeal, PVP, and stearic acid. Then, the remainder is added less the urea. The temperature controller is set to 40° C., allowing the temperature to decline. When the temperature is down to 50° C., the urea is added in portions as follows: 8 parts of 100, 8 parts, 8 parts, 16 parts, 16 parts, 16 parts, remainder. Care is taken that the temperature is 40° C. or higher on each addition. After the last urea addition, and after the temperature has again reached 40° C., the regulator is then set to 25° C., and the composition is agitated for 30 minutes. Aerosol dispensers can be filled with the composition at 25° C., and with stiffing during filling.

Definitions

The following terms shall have, for the purposes of this application, the respective meanings set forth below.

Effective Amount

To treat the indications of the invention, an effective amount of a urea will be recognized by clinicians but includes an amount effective to treat, reduce, alleviate, ameliorate, eliminate or prevent one or more symptoms of the disease sought to be treated or the condition sought to be avoided or treated, or to otherwise produce a clinically recognizable favorable change in the pathology of the disease or condition. In effective amount can be a dermatological treatment effective concentration of urea.

Publications and references, including but not limited to patents and patent applications, cited in this specification are herein incorporated by reference in their entirety in the entire portion cited as if each individual publication or reference were specifically and individually indicated to be incorporated by reference herein as being fully set forth. Any patent application to which this application claims priority is also incorporated by reference herein in the manner described above for publications and references.

While this invention has been described with an emphasis upon preferred embodiments, it will be obvious to those of ordinary skill in the art that variations in the preferred devices and methods may be used and that it is intended that the invention may be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications encompassed within the spirit and scope of the invention as defined by the claims that follow.

What is claimed:

1. A non-greasy, water-based foamable urea composition comprising:

(a) urea 20-50% by weight;

(b) one or more carboxylic acid containing lipophilic components; and

(c) a titrant in an amount such that at least a portion of the one or more carboxylic acid containing lipophilic components are in ionized form.

2. The non-greasy, water-based foamable urea composition of claim **1**, wherein the one or more carboxylic acid containing lipophilic components comprises a fatty acid.

3. The non-greasy, water-based foamble urea composition of claim **1**, wherein the titrant is triethanolamine.

4. The non-greasy, water-based foamable urea composition of claim **2**, wherein the fatty acid is present in an amount of from 1-5% by weight.

5. The non-greasy, water-based foamable urea composition of claim **1**, further comprising a frothing agent.

6. The non-greasy, water-based foamable urea composition of claim **5**, wherein the frothing agent is present in an amount of 0.3-4% by weight.

7. The non-greasy, water-based foamable urea composition of claim **1**, further comprising a humectant.

8. The non-greasy, water-based foamable urea composition of claim **7**, wherein the humectant is present in an amount of from 0.5-7% by weight.

9. The non-greasy, water-based foamable urea composition of claim **7**, wherein the humectant is selected from glycerol, propylene glycol, other polyols, polydextrose, lactic acid.

10. The non-greasy, water-based foamable urea composition of claim **7**, comprising urea 40% by weight, povidone, propylene glycol, glycerin, dimethicone, triethanolamine, polysorbate 20, phenoxyethanol, parabens, homogenized oatmeal, and water.

11. The non-greasy, water-based foamable urea composition of claim **7**, comprising urea 35% by weight, povidone, propylene glycol, glycerin, dimethicone, triethanolamine, polysorbate 20, phenoxyethanol, parabens, lactic acid, and water.

12. The non-greasy, water-based foamable urea composition of claim **1**, further comprising a soothing agent.

13. The non-greasy, water-based foamable urea composition of claim **12**, wherein the soothing agent is present in an amount of from 0.02-0.2% by weight.

14. The non-greasy, water-based foamable urea composition of claim **12**, wherein the soothing agent comprises homogenized oatmeal.

15. The non-greasy, water-based foamable urea composition of claim **1**, further comprising an emollient.

16. The non-greasy, water-based foamable urea composition of claim **15**, wherein the emollient is present in an amount of from 0.5-2% by weight.

17. The non-greasy, water-based foamable urea composition of claim **1**, further comprising one or more hydrophilic polymers.

18. The non-greasy, water-based foamable urea composition of claim **17**, wherein the one or more hydrophilic polymers are present in an amount of from 0.5-1.5% by weight.

19. The non-greasy, water-based foamable urea composition of claim **17**, wherein the one or more hydrophilic polymers are selected from polyvinyl pyrrolidone, polyethylene glycol, starch, cellulose, methyl cellulose, hydroxymethyl celluslose, other water-soluble derivatives of cellulose, water soluble derivatives of starch, or carbomers.

20. The non-greasy, water-based foamable composition of claim **17**, wherein the one or more carboxylic acid containing lipophilic components is stearic acid.

21. The non-greasy, water-based foamable urea composition of claim **1**, further comprising a propellant.

22. The non-greasy, water-based foamable urea composition of claim **20**, wherein in the propellant is selected from propane, butane, isobutene, other hydrocarbons, hydrofluorocarbons, chlorofluorocarbons.

23. An aerosol delivery device comprising the composition of claim **1** and a propellant.

24. A method of treating one or more indications of dermatitis, psoriasis, zerosis, ichthyosis, ecezema, keratosis, keratoderma, dry and rough skin, corns, calluses, damaged or ingrown and devitalized nails comprising applying the composition of claim **1** to the skin of a patient in need thereof.

* * * * *

EXHIBIT 2

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(54) **SALICYLIC ACID COMPOSITION**

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(57) **ABSTRACT**

Provided, among other things, is a delivery module for water-based salicylic acid composition comprising: an aerosol delivery system; within the aerosol delivery system, the salicylic acid composition comprising 0.5% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, the salicylic acid composition having a viscosity low enough to support aerosol delivery, and the salicylic acid composition effective to form a foam upon propellant-driven aerosol delivery; and within the aerosol delivery system, a propellant, wherein the salicylic acid composition is non-irritating and has a non-watery feel.

SALICYLIC ACID COMPOSITION

[0001] This application claims the priority of Ser. No. 61/105,557, filed 15 Oct. 2008.

[0002] The present invention relates to a composition of salicylic acid, which can be used to treat acne, psoriasis, calluses, corns, keratosis pilaris, warts, dandruff, and the like.

[0003] The dermatological utility of salicylic acid has been attributed to its causing skin cells to slough off. Commercial available topical compositions are often 17% (w/w). Salicylic acid has been reported to be antiseptic and antifungal. Salicylic acid can also be used to treat dermatitis, such as Lichen simplex.

[0004] Dermatological compositions of salicylic acid have been formulated in oily bases (lotions) and gels. Oil-based formulations provide a protective layer and localize the salicylic acid on the skin. These oil-based also facilitate formulating salicylic acid at useful concentrations and at the relatively low pH values that facilitate the dermatological actions of salicylic acid. Gel-based products facilitate formulation with a relatively large aqueous phase.

[0005] For foam-forming compositions based on emulsions, the compounding issues for salicylic acid are significant. Prior art foam formulations and formulating methods are susceptible to having the salicylic acid form non-uniformities such as lumps. These formulations and formulating methods tend to use alcohols and are also susceptible to insufficient foaming, and insufficient retention of water after application of the foam to a patient. When applied to a patient, the foams tend to melt or breakdown, with the alcohol evaporating.

[0006] A format that has been used for making dermatological foams is that of a urea product on the market. That product is believed to rely heavily on oils, such as Shea butter and sunflower oil, though it is said to have some amount of stearic acid. Given the amount of oils, this format may be usable for salicylic acid. When used to deliver urea, the format leaves a wet, watery layer at the site of application.

[0007] The present invention initially addressed many of these problems with a foam. It has now believed that many of these advantages are obtained with emulsions formulated as creams, gels, lotions, milks, and the like.

SUMMARY OF THE INVENTION

[0008] Provided, in one embodiment, is a delivery module for water-based salicylic acid composition comprising: an aerosol delivery system; within the aerosol delivery system, the salicylic acid composition comprising 0.5% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, the salicylic acid composition having a viscosity low enough to support aerosol delivery, and the salicylic acid composition effective to form a foam upon propellant-driven aerosol delivery; and within the aerosol delivery system, a propellant, wherein the salicylic acid composition is non-irritating and has a non-watery feel. The composition in the system can contain, for example, by weight: salicylic acid 0.5-10%; optionally fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10% ; hydrophilic polymer(s) 0.05-5%; and frothing agent(s) 3-11%. In certain embodiments, the polyalkyleneglycol-fatty acid ester component is the predominant component among the fatty acid, analogous alkyl amine and polyalkyleneglycol-fatty acid ester components.

[0009] Also provided, in one embodiment, is a salicylic acid composition comprising: A. salicylic acid 0.5-10%; B. optionally fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10%; C. hydrophilic polymer(s) 0.05-5%; and D. frothing agent(s) 1-11%, wherein the salicylic acid composition is effective to form a foam, and is non-irritating and has a non-watery feel. Additionally provided is a method of formulating the salicylic acid composition comprising adding the salicylic acid in an oil phase to a water solution comprising substantially all of hydrophilic polymer(s), the admixture providing substantially all of the components A through D. This composition also provides a non-irritating and non-watery feel in a bulk form, prior to aerosol delivery, and may in fact be delivered without a propellant, in the non-aerosolized form, or other emulsion forms such as gels, creams, lotions, and the like.

[0010] Further provided, in another embodiment, is a method of treating acne, psoriasis, calluses, corns, keratosis pilaris, dermatitis, warts or dandruff comprising applying an aerosol-driven foam to affected skin a foamed, non-greasy, water-based salicylic acid composition comprising: the salicylic acid composition comprising 0.5% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, the salicylic acid composition having a viscosity low enough to support aerosol delivery, and the salicylic acid composition effective to form a foam upon propellant-driven aerosol delivery, wherein the salicylic acid composition is non-irritating and has a non-watery feel.

[0011] Also provided, in another embodiment, is a method of treating acne, psoriasis, calluses, corns, keratosis pilaris, dermatitis, warts or dandruff comprising applying to affected skin a non-greasy, water-based salicylic acid composition comprising: the salicylic acid composition comprising 0.5% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, wherein the salicylic acid composition is non-irritating and has a non-watery feel.

DETAILED DESCRIPTION OF THE INVENTION

[0012] In certain embodiments, the formulation of the invention provides a non-irritating foam. Irritation is measured by ISO 10993-10: 2002 Standard, "Biological Evaluation of Medical Devices, Part 10-Tests for Irritation and Sensitization," pp. 6-10, 21, which testing method is incorporated herein by reference. In particular, for each test site on shaved dorsal skin of an albino rabbit, gauze incorporating 0.5 mL of test material or negative control material is applied. One test and one control site are used on each side of the paravertebral skin. The infused gauzes are covered with tape-backed gauze. The trunk of the rabbit is wrapped in elastic bandage secured by hypoallergenic tape. After a minimum of 24 hours, the coverings are unwrapped. Observations are made at 60 min ±2, 24 h±2, 48h±2 and 72 h±2 post unwrapping. Tissue reactions are rated for gross evidence of erythema and edema.

[0013] For a given rabbit, values for each test site and each of the 24 h, 48 h and 72 h measurements are totaled, and divided by six (2 tests sites×3 measurements). Control values were treated in the same way. For all rabbits, these test values were summed, normalized against the summed values for the negative controls, and divided by the number of animals. A negligible, slight, moderate or severe response is categorized based on the Primary Irritation Index:

Response Category	Comparative Mean Score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

[0014] By "non-irritating" it is meant that compositions according to this embodiment of the invention illicit a Negligible Primary Irritation Index.

[0015] The non-irritating quality of these embodiments is surprising in view of the surfactants often found in these embodiments. While not being bound by theory, it is believed that water and appropriate selection of relatively mild surfactants, as illustrated herein, may contribute to the non-irritating quality of the foam.

[0016] In certain embodiments, the foam of the invention has a "non-greasy feel" when applied. A non-greasy feel is measured in reference to a comparison of the feel of the Example 1 composition (non-greasy standard) of U.S. application Ser. No. 12/016,371, filed Jan. 18, 2008 (US2008/175793), applied to skin at 1 mg/cm^2, compared to the oil-based product described in the Table at Column 3 of U.S. Pat. No. 5,919,470 (Bradley Pharmaceuticals, Inc., greasy standard), applied in the same amount. Application includes working the foam into the skin. While the feel of compositions of the invention may vary, in making the comparison between the non-greasy standard, the greasy standard, and the prospective non-greasy composition, it will be apparent which category the prospective composition falls within. The non-greasy skin feel may be moist and smooth feeling, but the difference in greasy feel relative to the greasy comparative shall be clear.

[0017] In certain embodiments, the foam of the invention has a "non-watery feel" when applied. A non-watery feel is a feel much like that of the Example 1 composition (non-watery standard) of U.S. application Ser. No. 12/016,371, filed Jan. 18, 2008 (U52008/175793), applied to skin at 1 mg/cm^2. A feel that, in contrast, is substantially more watery, is disqualified.

[0018] In certain embodiments, the foam of the invention is a stable foam, meaning that when applied to the skin at one of 1, 2 or 3 mg/cm^2 and not worked into the skin, the foam remains a stably adherent foam for 30 seconds or more. In some cases, the foam remains a stably adherent foam for 60 seconds or more, 120 seconds or more, 150 seconds or more or 180 seconds or more. While stable, the foam can be worked into the patient's skin.

[0019] In certain embodiments, the foam-forming composition of the invention is essentially free of C1 to C6 alcohols. In certain embodiments, the foam-forming composition is essentially free of C1 to C5 alcohols. In certain embodiments, the foam-forming composition is essentially free of C1 to C4 alcohols. By essentially free it is meant that such alcohols may be present in minor amounts, as may be useful for example for compounding, but are not present in an amount that one of skill in the art of pharmaceutical foam formulating would select to stabilize the salicylic acid or the emulsion of a foam-forming composition. In these embodiments, the amount of such alcohols is less than about 8 wt %. In certain embodiments, the amount of such alcohols is than about 5%, or 2%, or 1% (wt/wt).

[0020] When worked into the skin, the compositions of the invention can have rapid absorption—contributing to their non-greasy and non-watery feels. The compositions can be easy to spread and are cosmetically elegant.

[0021] Salicylic acid can be present in dermatologically effective amount. For example, it can be present in an amount from A or above, from B or below, or from A to B (inclusive, optionally exclusive, of the endpoints), where A is 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0 or 9.5% wt; and B is 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0, 9.5, 10.0%, 15% or 20% wt. (All ranges in this specification are inclusive, and optionally exclusive, of the endpoints.)

[0022] The composition can contain lipophilic components (inclusive of acid forms of salicylic acid) that are believed to help distribute salicylic acid (inclusive of its salts) on and into the skin. A major portion of such lipophilic components can be amphiphates in amounts effective to stabilize the lipophilic components in solution and/or emulsified. Example amphiphates are fatty acids, which can be substantially or essentially ionized, wherein the salt is soluble in the aqueous solution of the salicylic acid composition. Other example amphiphates are polyalkyleneglycol-fatty acid esters. Further examples are alkyl amines with one alkyl per amine having a size distribution analogous to that of an appropriate fatty acid composition. Further examples are nonionic detergents.

[0023] The lipophilic components are, in certain embodiments, non-greasy, meaning that in the aggregate of the formulation, as formulated in the foam-forming composition, they are non-greasy.

[0024] The fatty acid can, for example, be of any composition found in a natural source, including hydrolysis of esterified fatty acids. Or, the fatty acid component can be hydrogenated to remove substantially all or a portion of any unsaturation. In certain embodiments, the fatty acid component or the alkyl moiety of the alkyl amine component is selected such that 50 mole % or more is C12 or higher, or C14, or C16 or higher. In certain embodiments, the fatty acid component or the alkyl moiety of the alkyl amine component is selected such that 50 mole % or more is C22 or lower, or C20 or lower, or C18 or lower. In certain embodiments, 75 mole % or more of the fatty acid component is from C12 or C14 or C16 to C22 or C20 or C18. In certain embodiments, 80 mole % or more, 85 mole % or more, 90 mole % or more, 95 mole % or more, 97 mole % or more, 98 mole % or more, or 99 mole % or more, meets one of the size parameters of this paragraph. In certain embodiments, the fatty acyl component of polyalkyleneglycol-fatty acid esters falls in one of the above ranges.

[0025] For carboxylic acid containing lipophilic components, useful salts include the alkali metal salts such as sodium or potassium salts; ammonium salts; salts formed with suitable organic bases, such as amine salts (such as triethyl amine, triethanol amine, or the like) and quaternary ammonium salts; or the like. Bivalent or trivalent salts can be used where they do not adversely affect solubility. For amine-containing lipophilic components, useful salts include maleates, fumarates, lactates, oxalates, methanesulfonates, ethanesulfonates, benzenesulfonates, tartrates, citrates, halides (e.g., hydrochlorides, hydrobromides), sulfates, phosphates, nitrates, and the like. As needed, the lipophilic components are provided such that a sufficient amount of constituent ionizable molecules are in ionized (salt) form to provide solubility. Such ionized forms can be prepared by

adding a titrant. Recitations of compositions described by their formation by titration include the equivalent compositions formed by pre-formed salts or otherwise.

[0026] The alkyl component of polyalkyleneglycol-fatty acid ester is generally C2-05, but predominantly C2. For example, ethyleneglycol can comprise 51% or more, 55% or more, 60% or more, 65% or more, 70% or more, 75% or more, 80% or more, 85% or more, 90% or more, 95% or more, 100% of the glycol units (molar basis). The number of glycol repeat units is generally a number from C or above, from D or below, or from C to D, where C is 10, 15, 20, 25, 30 or 35, and D is 60, 55, 50 or 45.

[0027] In certain embodiments, where present, the fatty acid, analogous alkyl amine, or polyalkyleneglycol-fatty acid ester components together (to the extent present) comprise an amount of E or more, F or less, of from E to F of the foam-forming composition, where E is 0.005, 0.008, 0.01, 0.05, 0.1,0.5, 1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9 or 6 wt %, and F is 0.02, 0.05, 0.1, 0.5, 1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 7, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 8. 8.1, 8.2, 8.3, 8.4, 8.5, 8.6, 8.7, 8.8, 8.9, 9, 9.1, 9.2, 9.3, 9.4, 9.5, 9.6, 9.7, 9.8, 9.9 or 10 wt %. Unless otherwise specified, the composition percentages for the foam-forming compositions are exclusive of propellant, such as propane or butane or the like.

[0028] In certain embodiments, the polyalkyleneglycol-fatty acid ester comprises an amount of E or more, F or less, of from E to F of the foam-forming composition. In certain embodiments, the amount of polyalkyleneglycol-fatty acid ester, among amphiphates in the foam-forming composition, is an amount of G or more, H or less, or from G to H of the amphiphates, where G is 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59 or 60 wt %, and H is 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 71, 72, 73, 74, 75, 76, 77, 78, 79 or 80 wt %. In certain embodiments, the polyalkyleneglycol-fatty acid ester comprises a predominant portion of the fatty acid, analogous alkyl amine, and polyalkyleneglycol-fatty acid ester components.

[0029] An emollient, if present, can be a silicone oil such as polydimethylsiloxane (i.e., dimethicone), petrolatum, or the like. In certain embodiments, the emollient(s) are an amount I or more, J or less, or I to J of the foam-forming composition, where I is 0.5, 0.6, 0.7, 0.8, 0.9, 1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9 or 4 wt %, and J is 0.6, 0.7, 0.8, 0.9, 1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 or 5 wt %. In certain embodiments, as among emollients and amphiphates in the foam-forming composition, the amount of emollient is an amount K or more, L or less, or K to L of the emollients and amphiphates, where K is 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19 or 20 wt %, and L is 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 or 25 wt %.

[0030] The amphiphates will typically include frothing agents, which for non-foam embodiments can be termed. Frothing agents can be non-ionic detergents, such as polyoxyethylene sorbitan fatty acid esters (such as Tween 80 (polyoxyethylene (20) sorbitan monolaurate), Polysorbate 20 (polyoxyethylene (20) sorbitan monooleate)), sorbitol fatty acid esters, octyly glucosides, PEGylated lipids and the like. In certain embodiments, the frothing agent(s) comprise an amount of M or more, N or less, of from M to N of the foam-forming composition, where M is 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9 or 6 wt %, and N is 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 7, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 8, 8.1, 8.2, 8.3, 8.4, 8.5, 8.6, 8.7, 8.8, 8.9, 9, 9.1, 9.2, 9.3, 9.4, 9.5, 9.6, 9.7, 9.8, 9.9, 10, 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7, 10.8, 10.9 or 11 wt %. For certain non-foam embodiments, the surfactant(s) comprise an amount of M' or more, N' or less, of from M' to N' of the foam-forming composition, where M' is 1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9 or 6 wt %, and N' is 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9, 5, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 5.7, 5.8, 5.9, 6, 6.1, 6.2, 6.3, 6.4, 6.5, 6.6, 6.7, 6.8, 6.9, 7, 7.1, 7.2, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 8, 8.1, 8.2, 8.3, 8.4, 8.5, 8.6, 8.7, 8.8, 8.9, 9, 9.1, 9.2, 9.3, 9.4, 9.5, 9.6, 9.7, 9.8, 9.9, 10, 10.1, 10.2, 10.3, 10.4, 10.5, 10.6, 10.7, 10.8, 10.9 or 11 wt %. The frothing agent(s) can comprise detergents with 2 or more, 3 or more, 4 or more, 5 or more fold difference in CMC. The frothing agents can, for example, have a CMC at 21° C. of 2×10^{-6}M to 10^{-4}M. In certain embodiments, where there are two or more frothing agents, the predominant (by wt) frothing agent can have the lower CMC vs the next most predominant frothing agent.

[0031] Hydrophilic polymer(s) can be present. These can be any non-toxic water soluble polymer(s) that (in the aggregate) stabilize foam and contribute to film formation on the skin. Examples include polyvinyl pyrrolidone, polyethylene glycol, starch, water-soluble derivatives of starch, cellulose, methyl cellulose, hydroxymethylcellulose, other water-soluble derivatives of cellulose, carbamers, or the like. For polyvinyl pyrrolidone, for example, useful average molecular weights include from 8,000 to 63,000, such as about 38,000. For all polymers used in the composition, the size can be sufficient to limit penetration of the horny layer of the skin, if skin penetration is an issue for the given polymer. In certain embodiments, hydrophilic polymer(s) are an amount O or more, P or less, or O to P of the foam-forming composition, where O is 0.05, 0.1, 0.2, 0.5, 0.6, 0.7, 0.8, 0.9, 1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9 or 4 wt %, and P is 0.6, 0.7, 0.8, 0.9, 1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.9, 4, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8, 4.9 or 5 wt %.

[0032] The composition can also contain a humectant, such as glycerol, propylene glycol, other polyols, polydextrose, lactic acid, or the like. In certain embodiments, humectant(s) are an amount M or more, N or less, or M to N of the foam-forming composition.

[0033] The wound-treating composition will typically contain a preservative or preservative system. Examples include Phenonip™ XB (a mixture of preservatives, believed to include phenoxyethanol, methylparaben, ethylparaben, butylparaben, propylparaben and isobutylparaben; from

Clariant UK Ltd., Leeds, UK), or a less complex preservative, such as one or two of methylparaben, ethylparaben, butylparaben, propylparaben and isobutylparaben.

[0034] The foam-forming composition will typically contain titrating agents such as triethylamine, NaOH, citrate, and the like. The amount is typically selected to provide a dermatologically acceptable pH, such as pH 4-8.

[0035] The salicylic acid compositions can be formulated as creams, lotions, gels, milks, foam-formers, and the like. Where creams or lotions are desired, these consistencies can be obtained by selection of hydrophilic polymers, and the amounts thereof. For example, these can include polymers that have a greater effect on increasing viscosity, in appropriate amounts. Such polymers can include, for example, appropriate carbamers, methy cellulose, hydroxyl alkyl cellulose, gum arabica, and the like. Addition of suitable hydrophilic copolymer permits the formation of different emulsion dosage forms that retain the same safety and efficacy properties as the foam but do not require the use of gaseous propellants for their delivery to the treatment area. In some cases, the amount of surfactant is reduced.

[0036] Suitable propellants include, for example, propane, butane, isobutene, other hydrocarbons, hydrofluorocarbons, chlorofluorocarbons (Cl/F/(H)/C), and the like. Dispensing systems include those available from Deutsche Präzision, Lindal Group (Schönberg, Germany), Coster (Milano, Italy) and SeaquistPerfect Dispensing (Cary, Ill.).

[0037] The invention further provides methods of formulating the foam-forming composition comprising adding the salicylic acid in an oil phase to a water solution comprising substantially all of hydrophilic polymer(s), the admixture providing substantially all of the components that are a, salicylic acid, b, fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s), c, hydrophilic polymer(s), and d, frothing agent(s). In certain embodiments, more oil-compatible humectants are proved in the oil phase, and relatively more hydrophilic humectants are added in the water solution.

[0038] To formulate 100 g, one can formulate all or a selection of the formulations defined by the combinations of the following options:

	Component	Amt. Options (g)
C1	Povidone	1.3, 1.5, 1.7
C2	Polyoxyethylene 40 stearate	3.0, 4.0, 5.0
C3	Methyl cellulose (1500 cp)	0.5, 1.0
C4	Stearic acid	0.013, 0.016
C5	Sodium citrate	2.0, 3.0
C6	Glycerol	1.0, 2.0
C7	Triethanol amine	2.5, 3.0
C8	Preservative	0.5
B	NaOH	As needed
A5	Salicylic acid	6.0
A2	Dimethicon	2.0, 2.5
A1	Propylene glycol	4.0, 5.0, 6.0
A3	Tween 80	4.0, 5.0
A4	Polysorbat 20	2.0, 3.0
	Water	Quantity Sufficient

[0039] The above can be formulated in 3 phases: mixing the A components; mixing B in a minor amount of the water; mixing the C components in the bulk of the water; adding the mixed A components to the mixed C components; and adding the mixed B components. The A components can be added to A1 stepwise in the order A2 to A5. The C components can be added to water stepwise in the order C1 to A8, with the water heated to promote mixing and solubilization. The mixed A components can be added in parts to the mixed C components, such as after the mixed A components have cooled, but still have an elevated temperature (over r.t.). The mixed B components are added (to A+B) after further cooling. The formulations can be tested for foam forming, foam stability, non-wet feel, irritation, non-greasy feel, and the like.

Effective Amount

[0040] To treat the indications of the invention, an effective amount of a salicylic acid will be recognized by clinicians but includes an amount effective to treat, reduce, alleviate, ameliorate, eliminate or prevent one or more symptoms of the disease sought to be treated or the condition sought to be avoided or treated, or to otherwise produce a clinically recognizable favorable change in the pathology of the disease or condition. In effective amount can be a dermatological treatment effective concentration of salicylic acid.

Misc. Embodiments

[0041] The invention further encompasses, among other things, the following numbered embodiments:

[0042] Embodiment 1. A delivery module for water-based salicylic acid composition comprising: an aerosol delivery system; within the aerosol delivery system, the salicylic acid composition comprising 0.5% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, the salicylic acid composition having a viscosity low enough to support aerosol delivery, and the salicylic acid composition effective to form a foam upon propellant-driven aerosol delivery; and within the aerosol delivery system, a propellant, wherein the salicylic acid composition is non-irritating and has a non-watery feel.

[0043] Embodiment 2. The delivery module of one of embodiments 1 or 3-7, wherein the salicylic acid composition comprises, by weight: salicylic acid 0.5-10%; optionally fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10%; hydrophilic polymer (s) 0.05-5%; and frothing agent(s) 3-11%.

[0044] Embodiment 3. The delivery module of one of embodiments 1-2 or 4-7, wherein the polyalkyleneglycol-fatty acid ester component is the predominant component among the fatty acid, analogous alkyl amine and polyalkyleneglycol-fatty acid ester components.

[0045] Embodiment 4. The delivery module of one of embodiments 1-3 or 5-7, wherein the salicylic acid composition provides a stable foam.

[0046] Embodiment 5. The delivery module of one of embodiments 1-4 or 6-7, wherein the salicylic acid composition is essentially free of Cl-C6 alcohols.

[0047] Embodiment 6. The delivery module of one of embodiments 1-5 or 7, wherein the salicylic acid composition provides a non-greasy feel.

[0048] Embodiment 7. The delivery module of one of embodiments 1-6, wherein the salicylic acid comprises 2-10%, and hydrophilic polymer(s) comprise 0.5-5%.

[0049] Embodiment 8. A salicylic acid composition comprising: A. salicylic acid 0.5-10%; B. optionally fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10%; and C. hydrophilic polymer(s)

0.05-5%; D. surfactant(s) 1-11%, wherein the salicylic acid composition is non-irritating and has a non-watery feel.

[0050] Embodiment 9. The delivery module of one of embodiments 8 or 10-13, wherein the polyalkyleneglycol-fatty acid ester component is the predominant component among the fatty acid, analogous alkyl amine and polyalkyleneglycol-fatty acid ester components.

[0051] Embodiment 10. The delivery module of one of embodiments 8-9 or 11-13, wherein the surfactants comprise 3-11% and the salicylic acid composition provides a stable foam.

[0052] Embodiment 11. The salicylic acid composition of one of embodiments 8-10 or 12-13, wherein the salicylic acid composition is essentially free of C1-C6 alcohols.

[0053] Embodiment 12. The salicylic acid composition of one of embodiments 8-11 or 13, wherein the salicylic acid composition provides a non-greasy feel.

[0054] Embodiment 13. The salicylic acid composition of one of embodiments 8-12, wherein the salicylic acid composition is effective to form a foam, the salicylic acid comprises 2-10%, and hydrophilic polymer(s) comprise 0.5-5%.

[0055] Embodiment 14. A method of treating acne, psoriasis, calluses, corns, keratosis pilaris, warts or dandruff comprising applying a non-greasy, water-based salicylic acid composition comprising: the salicylic acid composition comprising 0.5% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, wherein the salicylic acid composition is non-irritating and has a non-watery feel.

[0056] Embodiment 15. The method of one of embodiments 14 or 16-21, wherein applied composition comprises fatty acid, analogous alkyl amine or polyalkyleneglycol-fatty acid ester, and wherein the polyalkyleneglycol-fatty acid ester component is the predominant component among the fatty acid, analogous alkyl amine and polyalkyleneglycol-fatty acid ester components

[0057] Embodiment 16. The method of one of embodiments 14-15 or 17-21, wherein the salicylic acid composition provides a stable foam.

[0058] Embodiment 17. The method of one of embodiments 14-16 or 18-21, wherein the salicylic acid composition is essentially free of Cl-C6 alcohols.

[0059] Embodiment 18. The method of one of embodiments 14-17 or 19-21, wherein the salicylic acid composition provides a non-greasy feel.

[0060] Embodiment 19. The method of one of embodiments 14-18 or 20-21, wherein the applied composition comprises: salicylic acid 0.5-10%; optionally fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10%; hydrophilic polymer(s) 0.05-5%; and frothing agent(s) 3-11%.

[0061] Embodiment 20. The method of one of embodiments 14-19 or 21, comprising applying an aerosol-driven foam to affected skin a foamed, non-greasy, water-based salicylic acid composition comprising: the salicylic acid composition comprising 2% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, the salicylic acid composition having a viscosity low enough to support aerosol delivery, and the salicylic acid composition effective to form a foam upon propellant-driven aerosol delivery, wherein the salicylic acid composition is non-irritating and has a non-watery feel.

[0062] Embodiment 21. The method of one of embodiments 14-21, wherein the applied composition comprises: salicylic acid 0.5-10%; optionally fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10%; hydrophilic polymer(s) 0.5-5%; and frothing agent(s) 3-11%.

[0063] Embodiment 22. A method of formulating the composition of one of embodiments 8-13 comprising adding the salicylic acid in an oil phase to a water solution comprising substantially all of hydrophilic polymer(s), the admixture providing substantially all of the components A through D.

[0064] Publications and references, including but not limited to patents and patent applications, cited in this specification are herein incorporated by reference in their entirety in the entire portion cited as if each individual publication or reference were specifically and individually indicated to be incorporated by reference herein as being fully set forth. Any patent application to which this application claims priority is also incorporated by reference herein in the manner described above for publications and references.

[0065] While this invention has been described with an emphasis upon preferred embodiments, it will be obvious to those of ordinary skill in the art that variations in the preferred systems and methods may be used and that it is intended that the invention may be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications encompassed within the spirit and scope of the invention as defined by the claims that follow.

What is claimed:

1. A delivery module for water-based salicylic acid composition comprising:

an aerosol delivery system;

within the aerosol delivery system, the salicylic acid composition comprising 0.5% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, the salicylic acid composition having a viscosity low enough to support aerosol delivery, and the salicylic acid composition effective to form a foam upon propellant-driven aerosol delivery; and

within the aerosol delivery system, a propellant, wherein the salicylic acid composition is non-irritating and has a non-watery feel.

2. The delivery module of claim **1**, wherein the salicylic acid composition comprises, by weight:

salicylic acid 0.5-10%;

hydrophilic polymer(s) 0.05-5%; and

frothing agent(s) 3-11%.

3. The delivery module of claim **1**, wherein the salicylic acid composition further comprises, by weight:

fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10%.

4. The delivery module of claim **1**, wherein the polyalkyleneglycol-fatty acid ester component is the predominant component among the fatty acid, analogous alkyl amine and polyalkyleneglycol-fatty acid ester components.

5. The delivery module of claim **1**, wherein the salicylic acid composition provides a stable foam.

6. The delivery module of claim **1**, wherein the salicylic acid composition is essentially free of C1-C6 alcohols.

7. The delivery module of claim **1**, wherein the salicylic acid composition provides a non-greasy feel.

8. The delivery module of claim **1**, wherein the salicylic acid comprises 2-10%, and hydrophilic polymer(s) comprise 0.5-5%.

9. A salicylic acid composition comprising
salicylic acid 0.5-10%;
hydrophilic polymer(s) 0.05-5%; and
surfactant(s) 1-11%, wherein
the salicylic acid composition is non-irritating and has a non-watery feel.

10. The salicylic acid composition of claim **9**, further comprising:
fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10%.

11. The salicylic acid composition of claim **9**, wherein the polyalkyleneglycol-fatty acid ester component is the predominant component among the fatty acid, analogous alkyl amine and polyalkyleneglycol-fatty acid ester components.

12. The salicylic acid composition of claim **9**, wherein the surfactants comprise 3-11% and the salicylic acid composition provides a stable foam.

13. The salicylic acid composition of claim **9**, wherein the salicylic acid composition is essentially free of C1-C6 alcohols.

14. The salicylic acid composition of claim **9**, wherein the salicylic acid composition provides a non-greasy feel.

15. The salicylic acid composition of claim **9**, wherein the salicylic acid composition is effective to form a foam, the salicylic acid comprises 2-10%, and hydrophilic polymer(s) comprise 0.5-5%.

16. A method of treating acne, psoriasis, calluses, corns, keratosis pilaris, warts or dandruff comprising applying a non-greasy, water-based salicylic acid composition comprising:
the salicylic acid composition comprising 0.5% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, wherein
the salicylic acid composition is non-irritating and has a non-watery feel.

17. The method of claim **16**, wherein the salicylic acid composition provides a stable foam.

18. The method of claim **16**, wherein the salicylic acid composition is essentially free of C1-C6 alcohols.

19. The method of claim **16**, wherein the salicylic acid composition provides a non-greasy feel.

20. The method of claim **16**, wherein the applied composition comprises:
salicylic acid 0.5-10%;
hydrophilic polymer(s) 0.05-5%; and
frothing agent(s) 3-11%.

21. The method of claim **20**, wherein the applied composition further comprises:
fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10%.

22. The method of claim **16**, comprising applying an aerosol-driven foam to affected skin a foamed, non-greasy, water-based salicylic acid composition comprising:
the salicylic acid composition comprising 2% or more salicylic acid by weight, lipophilic component(s), and a frothing agent, the salicylic acid composition having a viscosity low enough to support aerosol delivery, and the salicylic acid composition effective to form a foam upon propellant-driven aerosol delivery, wherein
the salicylic acid composition is non-irritating and has a non-watery feel.

23. The method of claim **22**, wherein the applied composition comprises:
salicylic acid 2-10%;
hydrophilic polymer(s) 0.5-5%; and
frothing agent(s) 3-11%.

24. The method of claim **23**, wherein the applied composition further comprises:
fatty acid(s) and/or analogous alkyl amine(s) and/or polyalkyleneglycol-fatty acid ester(s) 0.005-10%.

25. A method of formulating the composition of claim **9** comprising adding the salicylic acid in an oil phase to a water solution comprising substantially all of hydrophilic polymer (s), the admixture providing substantially all of the components A through D.

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